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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,977	02/15/2000	James W. Soong		5482

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James W. Soong
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[REDACTED]
EXAMINER

BLECK, CAROLYN M

[REDACTED]
ART UNIT PAPER NUMBER

3626

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/500,977	SONG, JAMES W.
	Examiner Carolyn M Bleck	Art Unit 3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 February 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) 1-20 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 15 February 2000.

Claims 1-20 are pending. An IDS statement has not been entered or considered.

Claim Objections

2. The claims are objected to because the lines are crowded too closely together, making reading and entry of amendments difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

3. Claim 14 is objected to because of the following informalities: at line 2 of claim 14, it appears the phrase "defining a defining" is grammatically incorrect. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application

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being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-4, 7-13, and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans (5,924,074).

(A) As per claim 1, Evans discloses a method for storage and retrieval of electronic medical records in a computer environment, such as a local or wide area network including portable computers or point of care system for data capture communicating with a patient data repository to store and organize data in a database (Fig. 1 and 24, col. 1 lines 5-10, col. 2 line 20 to col. 3 line 42, col. 4 line 64 to col. 5 line 27, and col. 16 lines 35-43) comprising:

(a) implementing the patient data repository using SQL to specify the semantics of the various components of the database management system (DBMS), including the structures and operations of the data model implemented by the DBMS and other components that support data definition, data access, security, and data administration of electronic medical records (col. 2 line 20 to col. 3 line 42, col. 4 line 64 to col. 5 line 27, col. 13 line 56 to col. 14 line 7, and col. 16 lines 35-53);

(b) providing a communication network, such as a local area network, a wide area network, and world wide web portion of the Internet, allowing communication

between the patient data repository at a first location and a point of care system, such as a desktop computer, laptop computer, or wireless pen computer, at a second location (Fig. 1 and 24, col. 1 lines 5-10, col. 2 line 20 to col. 3 line 42, col. 4 line 64 to col. 5 line 27, col. 12 line 55 to col. 13 line 30, and col. 16 lines 35-43); and

(c) retrieving and annotating of the electronic medical records of a patient by entering patient data using the point of care system, such as a desktop computer, laptop computer, or wireless pen computer (Fig. 1 and 24, col. 1 lines 5-10, col. 2 line 20 to col. 3 line 42, col. 4 line 64 to col. 5 line 27, col. 6 line 36 to col. 7 line 5, col. 12 line 55 to col. 13 line 30, col. 16 lines 35-43, and col. 18 lines 43-67).

(B) As per claim 2, Evans discloses using the point of care system, such as a desktop computer, laptop computer, or wireless pen computer, to enter, capture, process, analyze, review, and annotate electronic medical records (Fig. 1 and 24, col. 5 lines 1-27, col. 6 line 10 to col. 7 line 5).

In addition, insofar as Applicant recites “create, modify, display, or initiate...”, it is irrelevant whether or not Evans discloses every single statement recited in the claim.

(C) As per claim 3, Evans discloses a method further comprising:

(a) creating an electronic medical record by capturing patient data, such as vital signs, x-ray images, and laboratory results, through a graphical user interface, wherein upon creation of a patient record, a patient locator creates a patient data structure

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having the patient ID and the patient's name, and wherein the patient data structure includes pointers to data structures having data within the patient record captured by the point of care system, such as vital signs, x-ray images, and laboratory results (col. 4 line 64 to col. 5 line 27 and col. 8 lines 29-60);

(b) communicating the electronic medical record from the point of care system to the patient data repository over a network (Fig. 1 and 24 and col. 2 line 45 to col. 3 line 3); and

(c) storing the electronic medical record in the database in the patient data repository (Fig. 1 and 24, col. 1 lines 5-10, col. 2 line 20 to col. 3 line 42, col. 4 line 64 to col. 5 line 27, and col. 16 lines 35-43).

(D) As per claim 4, Evans discloses a method further comprising providing a data handler to convert selected patient data into a selected format for organization and storage of patient data in the patient data repository, wherein the patient data repository organizes and stores patient data and is comprised of a patient locator having a patient identifier and a data manager, in communication with the patient locator, to organize patient data for storage and retrieval using the patient identifier (col. 16 line 54 to col. 17 line 29).

(E) As per claim 7 and 18, Evans discloses a method for storage and retrieval of electronic medical records in a computer environment, such as a local or wide area network or world wide web portion of the Internet, including portable computers or point

of care system for patient data capture by a health care provider communicating with a patient data repository to store and organize data in a database (Fig. 1 and 24, col. 1 lines 5-10, col. 2 line 20 to col. 3 line 42, col. 4 line 64 to col. 5 line 27, and col. 16 lines 35-43) comprising:

- (a) using a point of care system communicating with a patient data repository, including database for storing patient information, over a network (Fig. 1 and 24, col. 1 lines 5-10, col. 2 line 20 to col. 3 line 42, col. 4 line 64 to col. 5 line 27);
- (b) providing a point of care system, such as a desktop computer, laptop computer, or wireless pen computer, including a graphical user interface to use a chart puller window enabling a healthcare provider to select an appropriate patient (Fig. 1, 3, and 24, col. 5 line 55 to col. 6 line 9, and col. 6 line 10 to col. 7 line 5);
- (c) using a point and click interface to access and annotate an electronic medical record of a patient displayed chart puller window (Fig. 1, 3, and 24, col. 5 line 55 to col. 6 line 9, and col. 6 line 10 to col. 7 line 5); and
- (d) storing the electronic medical record in the database in the patient data repository (Fig. 1 and 24, col. 1 lines 5-10, col. 2 line 20 to col. 3 line 42, col. 4 line 64 to col. 5 line 27, and col. 16 lines 35-43).

(F) As per claim 8, Evans discloses accessing and entering patient data through a web browser on the point of care system provided by a web server in communication with the patient data repository or server, wherein the entered patient data is communicated

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to the patient data repository via a network such as the world wide web (Fig. 24, col. 6 line 36 to col. 7 line 5, and col. 12 line 55 to col. 14 line 25).

(G) Claims 9-11 repeats the same limitations of claims 2-4, and is therefore rejected for the same reasons given for those claims, and incorporated herein.

(H) As per claim 12, Evans discloses storing the patient record in the patient data repository, wherein the patient record includes information consisting of the health care provider, condition of the patient and clinical data, diagnosis and procedure information, time of entry of data, and the date of the healthcare provider services (Fig. 3, 6-8, and 19-20, col. 4 line 64 to col. 5 line 55, col. 6 line 10-35, col. 8 line 61 to col. 9 line 36, col. 10 lines 35-58, and col. 11 lines 9-30).

In addition, insofar as Applicant recites "from the group consisting of...", it is irrelevant whether or not Evans discloses every single statement recited in the claim.

(I) As per claim 13, Evans discloses a method further comprising:

(a) examining the patient using the point of care system at a healthcare provider's location to make a diagnosis and to treat the patient's condition and obtain additional clinical data such as laboratory tests and x-rays, and prescribe medications (col. 4 line 64 to col. 5 line 27 and col. 5 lines 29-55); and

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(b) creating an electronic medical record by capturing patient data based on the patient examination, such as vital signs, x-ray images, and laboratory results, through a graphical user interface, wherein upon creation of a patient record, a patient locator creates a patient data structure having the patient ID and the patient's name, and wherein the patient data structure includes pointers to data structures having data within the patient record captured by the point of care system, such as vital signs, x-ray images, and laboratory results (col. 4 line 64 to col. 5 line 27 and col. 8 lines 29-60).

(J) Claim 19 repeats the same limitations of claims 1-2 and 7, and is therefore rejected for the same reasons given for those claims, and incorporated herein.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5, 14-15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) as applied to claims 1, 7, and 19, and further in view of Walker et al. (6,302,844).

(A) As per claims 5, 14, and 20, the relevant teachings of Evans are as discussed in the rejections above, and incorporated herein.

Evans fails to expressly disclose a method further comprising defining a threshold event, programming the site computer or the database with the threshold event, analyzing the records capable of having information regarding satisfaction of the threshold event, and providing predetermined notifications upon satisfaction of the threshold event. However, Evans includes identifying patient records that a healthcare provider needs for appointments scheduled at a future time (col. 4 line 64 to col. 5 line 27 and col. 9 lines 19-21).

Walker discloses a method for analyzing data from remote patient monitoring equipment comprising:

- (a) receiving data representing at least one parameter of a patient and determining whether the received data is indicative of an anomaly or within appropriate boundaries (col. 1 line 65 to col. 2 line 27, col. 3 lines 9-26, col. 4 lines 23-48, and col. 5 line 58 to col. 6 line 2);
- (b) providing a central server to examine the data to determine if at least one of the parameters is within appropriate boundaries (col. 4 lines 23-48);
- (c) analyzing the data, including a patient's medical record, wherein the data is capable of having information indicative of whether an anomaly exists or whether the data is within appropriate boundaries (col. 1 line 65 to col. 2 line 27, col. 3 lines 9-26, col. 4 lines 23-48, and col. 5 line 58 to col. 6 line 2); and
- (d) communicating information automatically to a physician or other user when an anomaly occurs using the central server, including databases (col. 1 line 65 to col. 2

line 27, col. 3 lines 9-26, col. 4 lines 23-48, col. 5 line 58 to col. 6 line 2, and col. 7 lines 12-44).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned component of Walker within the method taught by Evans with the motivation of increasing the quality of healthcare provided to patients and administered by healthcare providers by identifying warning signs of a medical condition in a patient's data (Walker; col. 1 lines 26-64).

(B) As per claim 15, the relevant teachings of Evans are as discussed in the rejections above, and incorporated herein.

Evans discloses storing a patient's billing and payment information in a patient's medical record (col. 1 lines 28-30), wherein a data manager is able to identify and analyze a patient's medical record for specific data stored within the record such as a particular appointment date (col. 9 lines 14-36). Evans fails to expressly disclose a threshold event relating to amounts owed by the patient to the healthcare provider, wherein a predetermined notification includes a request to make payments to the healthcare provider.

Walker discloses a method comprising:

(a) receiving data representing at least one parameter of a patient and determining whether the received data is indicative of an anomaly or within appropriate boundaries and data representing an amount of money due for a particular service

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provided by a physician (col. 1 line 65 to col. 2 line 27, col. 3 lines 9-26, col. 4 lines 23-48, col. 5 line 58 to col. 6 line 2, and col. 11 lines 49-67);

(b) providing a central server to examine the data to determine if at least one of the parameters is within appropriate boundaries (col. 4 lines 23-48);

(c) analyzing the data, including a patient's medical record, wherein the data is capable of having information indicative of whether an anomaly exists or whether the data is within appropriate boundaries (col. 1 line 65 to col. 2 line 27, col. 3 lines 9-26, col. 4 lines 23-48, and col. 5 line 58 to col. 6 line 2); and

(d) communicating information automatically to a physician or other user when an anomaly occurs using the central server, including databases (col. 1 line 65 to col. 2 line 27, col. 3 lines 9-26, col. 4 lines 23-48, col. 5 line 58 to col. 6 line 2, and col. 7 lines 12-44).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned feature of Walker, mainly utilizing threshold values when analyzing patient data resulting in notifying a patient of a particular event such as a payment amount due, within the method taught by Evans with the motivation of properly compensating a healthcare provider for services and providing an effective means to access and share information between a healthcare provider and other entity such as a patient (Evans; col. 2 lines 5-20).

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8. Claims 6 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) as applied to claims 1 and 7, and further in view of Bardy (6,277,072).

(A) As per claims 6 and 16-17, the relevant teachings of Evans are as discussed in the rejections above, and incorporated herein.

Evans discloses a method further comprising:

- (a) providing several levels of security for access by a user to patient data through a web browser (col. 13 lines 19-30 and col. 15 lines 16-32);
- (b) providing through the electronic medical records system a tiered password system, wherein a system administrator may have global access to any patient data, wherein physicians may have access to only patient records within their specialty, and wherein nurses and staff may have access to only those patient records within their immediate care (col. 13 lines 19-30 and col. 15 lines 16-32);
- (c) capturing each piece of data at the point of care system at the time of entry including time and healthcare provider identification, wherein the electronic medical records system provides a complete audit trail for all patient data stored in the patient data repository (Fig. 1, col. 2 lines 31-35, col. 9 line 37 to col. 10 line 16, and col. 14 lines 42-48); and
- (d) remotely accessing an electronic medical record stored in the patient data repository through a web browser by an interested person, such as a physician (Fig. 1 and col. 13 lines 19-30).

Evans fails to expressly disclose automatically transmitting a particular record to an interested person when the particular record has been received by the computer. However, Evans includes remotely accessing an electronic medical record stored in the patient data repository through a web browser by an interested person, such as a physician (Fig. 1 and col. 13 lines 19-30).

Bardy discloses a feedback module to provide automated feedback to a user through electronic mail, wherein a patient care record, including analysis of data stored in the record, are provided to a user upon receipt of the record to a database module (col. 9 lines 1-31 and col. 9 line 54 to col. 10 line 47).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned component of Bardy within the method of Evans with the motivation of reducing the amount of time to access patient medical records (Bardy; col. 2 lines 37-39).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a medical alerting system and procedure for providing a message representative of a healthcare condition to one or more target recipients (5,754,111), a system and method for managing patient medical information (5,772,585), a networked system for communicating medical information to an individual and for remotely monitoring the individual (5,997,476), a

system for controlling a medical device over a network (6,304,788), and a medical records system that creates and maintains all patient data electronically (6,347,329).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The examiner can normally be reached on Monday-Friday, 8:30am – 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

11. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

- | | |
|----------------|--|
| (703) 305-7687 | [Official communications; including After Final communications labeled "Box AF"] |
| (703) 746-8374 | [Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"] |

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Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive,
Arlington, VA, 7th Floor (Receptionist).



CB

August 22, 2002



DINH X. NGUYEN
PRIMARY EXAMINER